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Proposed Registration Decision PRD2011-01

Sulfentrazone

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Overview

Proposed Registration Decision for Sulfentrazone

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Sulfentrazone Technical Herbicide and Authority 480 Herbicide containing the technical grade active ingredient sulfentrazone for use on chickpeas in the Prairie Provinces to control a variety of weeds.

Sulfentrazone Technical Herbicide (Registration Number 29011) and Authority 480 Herbicide (Registration Number 29012) are conditionally registered in Canada. The detailed review for Sulfentrazone Technical Herbicide and Authority 480 Herbicide can be found in Evaluation Report ERC2010-08, *Sulfentrazone*. The current applications were submitted to convert Sulfentrazone Technical Herbicide and Authority 480 Herbicide from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessments of Sulfentrazone Technical Herbicide and Authority 480 Herbicide.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on sulfentrazone, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on sulfentrazone, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation of this consultation document.

What Is Sulfentrazone?

Sulfentrazone is a selective soil applied herbicide, i.e. a herbicide applied before the crop and weeds have emerged from the ground. It belongs to the triazolinone chemical class and controls plants by disrupting cell membranes.

Health Considerations

Can Approved Uses of Sulfentrazone Affect Human Health?

Sulfentrazone is unlikely to affect your health when used according to the label directions.

Exposure to sulfentrazone may occur through diet (food and water), or when handling or applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 300-times higher (and often much higher) than levels to which humans are normally exposed when products containing sulfentrazone are used according to label directions.

3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Although the skin sensitization study did not show any effects, the dose selection for that study was not considered to be adequate according to the guideline used. As such, the technical grade active ingredient, sulfentrazone, was considered to be a potential skin sensitizer. Therefore, the label statement "Potential Skin Sensitizer" is required. Also, sulfentrazone was considered to be moderately toxic through the oral route, but of low toxicity through the dermal and inhalation routes. Although sulfentrazone was found to be minimally irritating to the eyes, it was not found to be irritating to the skin. The end-use product, Authority 480 Herbicide, was of low toxicity through the oral, inhalation and dermal routes. It was not irritating to the skin or to the eyes and was not considered to be a potential skin sensitizer.

Sulfentrazone was not considered to be genotoxic or cause cancer in animals. However, there were some indications that sulfentrazone caused damage to the developing fetus and the reproductive system. Although sulfentrazone did not cause irreversible nervous system damage, it was considered to cause some neurotoxicity at doses causing other serious effects such as mortality. Health effects in animals given sulfentrazone on a daily basis for prolonged periods of time included clinical anaemia, liver and kidney effects. There were also effects on body weight and body weight gain.

The risk assessment was conducted to ensure that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children, nursing mothers and women of child bearing age). Only those uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Residues in Water and Food

Aggregate dietary intake estimates (food plus water) revealed that the general population and infants, the subpopulation which would ingest the most sulfentrazone relative to body weight, are expected to be exposed to less than 53.7% of the acceptable daily intake. Based on these estimates, the chronic dietary risk from sulfentrazone is not of concern for all population sub-groups.

Aggregate (food and water) dietary intake estimates for women aged 13-49 years was 21.13% of the acute reference dose and for the general population was 0.77% of the acute reference dose, which are not a health concern.

The *Food and Drugs Act* (FDA) prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for FDA purposes through the evaluation of scientific data under the *Pest Control Products Act*. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Residue trials conducted throughout the United States on asparagus, cabbage, horseradish, dry shelled beans, dry shelled peas, mint, soybean and sunflower and in Canada on chickpeas using sulfentrazone were acceptable. The proposed MRLs for sulfentrazone in Canada in or on food can be found in the Proposed Maximum Residue Limit PMRL2010-32, *Sulfentrazone*.

Occupational Risks From Handling Authority 480 Herbicide

Occupational risks are not of concern when Authority 480 Herbicide is used according to label directions, which include protective measures.

Farmers and custom applicators who mix, load or apply, as well as field workers re-entering freshly treated fields, can come in direct contact with Authority 480 Herbicide residues on the skin. Therefore, the label specifies that anyone mixing or loading Authority 480 Herbicide must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Anyone applying Authority 480 Herbicide must wear a long-sleeved shirt, pants and shoes plus socks. The label also requires that workers do not enter treated fields for 12 hours after application. Taking into consideration these label statements, the number of applications and the expected exposure period for handlers and workers, risks to these individuals are not a concern.

For bystanders, exposure is expected to be much less than that for workers and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Sulfentrazone Is Introduced Into the Environment?

Sulfentrazone is persistent in soil. Soil residues are expected to carryover to the following growing season and have a high potential to leach to groundwater. The extent to which sulfentrazone leaches and/or persists in soil is related to soil texture, organic matter and soil pH. Based on results of field studies, sulfentrazone is persistent in groundwater, but is only slightly persistent in surface water ecosystems. Without risk reduction measures, sulfentrazone may impact non-target terrestrial plants adjacent to the treatment area.

Sulfentrazone enters the terrestrial environment when used as a herbicide on chickpeas in the Prairie Provinces. Once in the terrestrial environment, sulfentrazone is persistent with the only route of transformation being slow aerobic biotransformation. Field studies show that sulfentrazone will carryover to the following use season. Sulfentrazone and the degradate, 3-carboxylic acid sulfentrazone (SCA), have properties which suggest they are highly mobile and have a high potential to leach. Soil properties such as texture, organic matter and pH influence soil mobility. Under alkaline conditions (pH > 6.5), sulfentrazone will be more susceptible to leaching. Field studies confirm that sulfentrazone leaches and slowly transforms to SCA with depth, and that both sulfentrazone and SCA may persist for an extended time in groundwater.

Sulfentrazone can enter aquatic ecosystems through spray drift and/or runoff from treated fields. In surface water ecosytems, sulfentrazone remains in the water column and is very susceptible to phototransformation. Based on field studies, it is not expected to persist in surface waters. Sulfentrazone does not bioconcentrate and is therefore unlikely to bioaccumulate.

The risk to the environment was assessed for the end-use product, Authority 480 Herbicide. Sulfentrazone is not expected to pose a risk to aquatic organisms and terrestrial invertebrates, birds and mammals. A risk to terrestrial plants was identified and can be mitigated with spray buffer zones.

Additional information was submitted and reviewed to address the data gaps identified in ERC2010-08. No additional information is required.

Value Considerations

What Is the Value of Authority 480 Herbicide?

Authority 480 Herbicide (Group 14) provides an alternative mode of action to commonly used herbicides for chickpea.

Authority 480 Herbicide, containing the active ingredient sulfentrazone at 480 grams per litre of product, is applied to bare land as a pre-plant or pre-emergence application (spring only) on the soil surface to provide control of common lamb's quarters, redroot pigweed, kochia and wild buckwheat in chickpea at a rate of 105 to 140 g a.i./ha in medium and fine textured soils in the Prairie Provinces only.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Authority 480 Herbicide to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone mixing or loading Authority 480 Herbicide and doing clean-up and repairs must wear a long-sleeved shirt, long pants, chemical-resistant gloves and shoes plus socks. Anyone applying the product must wear a long-sleeved shirt, long pants and shoes plus socks. The label also specifies that workers not enter treated fields for 12 hours, and apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools

and recreational areas is minimal, taking into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings.

Environment

Currently, spray buffer zones of one metre are required to protect terrestrial plants from sulfentrazone spray drift. As sulfentrazone is persistent and will carryover in soil, it is recommended that any product containing sulfentrazone not be used in areas treated with this product during the previous season. To advise the user of the potential for leaching, advisory statements are included on the label.

Value

To minimize the carryover of sulfentrazone, due to the persistence of the active ingredient in soils of certain textures, Authority 480 Herbicide is to be applied once every 24 months only and should not be applied:

- on any coarse textured soils;
- on fine textured soils with less than 1.5% organic matter;
- on any type of soil with an organic matter content greater than 6%, and
- on soils with a pH of 7.8 or greater.

Registration is limited to the Prairie Provinces for use on chickpea. Precautionary label statements are required regarding the intervals between application and regarding re-cropping intervals.

Next Steps

Before making a final registration decision on sulfentrazone, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on sulfentrazone (based on the Science Evaluation of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Sulfentrazone

1.0 The Active Ingredient, Its Properties and Uses

For the chemistry of the technical and end-use products, please refer to Evaluation Report ERC2010-08, *Sulfentrazone*.

2.0 Methods of Analysis

2.1 Methods for Analysis of the Active Ingredient

Please refer to ERC2010-08.

2.2 Method for Formulation Analysis

Please refer to ERC2010-08.

2.3 Methods for Residue Analysis

Please refer to ERC2010-08 for previously reviewed environmental residue analytical methods. For this application, high-performance liquid chromatography methods with mass or tandem mass spectrometry (HPLC-MS or HPLC-MS/MS) were developed and proposed for data generation and enforcement purposes. These methods fulfilled the requirements with regards to selectivity, accuracy and precision at the respective method limit of quantitation. Acceptable mean recoveries (70–120%) were obtained in soil and fish matrices. Methods for residue analysis reviewed for this application are summarized in Appendix I, Table 1.

Refer to ERC2010-08 for a detailed assessment of the methods of dietary residue analysis for sulfentrazone.

3.0 Impact on Human and Animal Health

Please refer to ERC2010-08 for a detailed assessment of the toxicological database for sulfentrazone.

3.1 Toxicology Summary

A detailed review of the toxicological database for the herbicide sulfentrazone was previously conducted and was summarized in ERC2010-08. As a condition of registration, a rationale comparing toxicological properties of the environmental metabolite sulfentrazone 3-carboxylic acid (SCA) to the parent, including any available toxicology data on SCA, was requested. No data were submitted, and a rationale provided by the registrant was deemed insufficient to

demonstrate that SCA is less toxic than the parent. Examination of the available scientific literature by the PMRA found no evidence to suggest that SCA is more toxic than the parent. As a result, PMRA will continue to consider the metabolite to be of equivalent toxicity to the parent unless the registrant wishes to refine the risk assessment by submitting data/information in the future indicating otherwise. Therefore, no amendments to the previous toxicology review were made and the initial health risk assessment stands.

3.2 Occupational and Residential Risk Assessment

Please refer to ERC2010-08 for a detailed evaluation of occupational and residential risk from the use of Authority 480 Herbicide.

3.3 Food Residues Exposure Assessment

Please refer to ERC2010-08 for a detailed food residue exposure assessment of Sulfentrazone Technical Herbicide and Authority 480 Herbicide.

4.0 Impact on the Environment

Please refer to the ERC2010-08 for a detailed assessment of the fate and behaviour of sulfentrazone and its environmental impacts.

Previously outstanding data requirements for sulfentrazone were related to the potential fate and effects of the active ingredient and the SCA transformation product in surface water, groundwater and the terrestrial environment. Information to address the outstanding requirements was submitted to the PMRA and reviewed.

New information on the potential fate of the active ingredient sulfentrazone, and the SCA transformation product in aquatic ecosystems (surface water), groundwater and the terrestrial environment were submitted. Below is an overview of recent findings:

Additional information on the physico-chemical properties of SCA
SCA is very soluble in water with a reported solubility of 1.92 g/L at pH 2.5. Its solubility in water is expected to be greater at environmentally relevant pHs. The estimated log K_{ow} is 1.41 indicating that bioaccumulation is unlikely.

Additional information on the environmental chemistry and fate of SCA
SCA is stable to hydrolysis at pH 5, pH 7 and pH 9.

The rate of photolysis varied with pH and photolysis is expected to be an important route of degradation at pH 7 and pH 9, but less at pH 4. The major transformation products produced under acidic conditions (pH 4) differed from those identified in the neutral (pH 7) and basic (pH 9) solutions. In the pH 4 solution, the major transformation products were M2 and M4. In the pH 7 and pH 9 solutions, the major transformation products were M1, M3 and M5. The chemical name and structure of the transformation products are presented in Appendix I, Table 2.

The results of the adsorption/desorption study submitted showed that SCA was very highly mobile in all soils tested. These results are consistent with the previously submitted laboratory column leaching studies reviewed under ERC2010-08 and the prospective groundwater monitoring studies reviewed for the current application.

Terrestrial Field Dissipation Study
In ERC2010-08, only one of the four terrestrial field dissipation studies submitted were relevant to the Canadian environment and none were relevant to the Prairie Provinces where sulfentrazone is intended for use. An additional study conducted in Manitoba (Ecoregion 9.2.1, clay loam soil) was required and submitted under the current application.

The results from the Manitoba site indicated that sulfentrazone is persistent in soil and has the potential to leach under field conditions. Sulfentrazone had a single first-order DT_{50} value of 283 days (DT_{90}: 941) and a double first-order half-life of 87 days (DT_{90}: 1200 days). Twenty percent (20%) of the applied residues carried over to the following season while 13% carried over to the second season (736 days). Sulfentrazone was detected down to 90 cm (372-493 days) and SCA was detected down to 75 cm (days 122-736).

The behaviour of sulfentrazone in the environment is influenced by soil characteristics such as soil type, texture and pH. The soil and climatic conditions for the Manitoba study are considered to be representative of the current registered use pattern. These results were considered with the previously submitted field study results reviewed under ERC2010-08.

Aquatic Field Dissipation Study
In ERC2010-08, an aquatic field dissipation study was required to further characterise the fate of sulfentrazone in surface waters. An aquatic field dissipation study conducted in Southern Manitoba (Ecoregion 9.2.1, clay loam soil) was submitted and reviewed.

The results indicated that sulfentrazone remained primarily in the surface waters with some residues reaching the subsurface layer. Methyl triazole, a major photolysis transformation product, increased in concentration and remained constant over the sampling period. No sulfentrazone or methyl triazole residues were measured in the sediment.

The single first order DT_{50} and DT_{90} values were 22 and 74 days, respectively.

The major route of dissipation of sulfentrazone under aquatic field conditions is likely phototransformation. Sulfentrazone is extremely susceptible to photolysis ($t_{1/2}$ = 12 hours at pH 5, 1 hour at pH 7 and pH 9) and there is no evidence of significant transformation via other routes (hydrolysis, biotransformation). Methyl triazole was a major transformation product identified in the laboratory aqueous photolysis studies at all pHs tested and was also measured in the aquatic field dissipation study.

Prospective Groundwater Monitoring studies

Three small-scale prospective groundwater monitoring studies were conducted in the state of Indiana, on the behalf of the US EPA, to evaluate the groundwater contamination potential of sulfentrazone and its major acid transformation product, SCA. The studies were selected based on soil and hydrogeologic criteria regarding vulnerability to leaching, as having 75th, 85th and 95th percentile vulnerability for potential groundwater contamination. The study procedures for the 75th and 95th percentile studies largely complied with regulatory standards, and were acceptable for review. The 85th percentile study was subject to a preliminary review, and was deemed unacceptable.

The results of the 95th and 75th percentile study showed that sulfentrazone leached through the soils of the vadose zone while slowly transforming to SCA.

In the 95th percentile study, sulfentrazone and SCA were detected in all eight of the shallow groundwater monitoring wells during the course of the 60-month study, and the concentrations showed a clear pattern of breakthough, peak and decline.

Sulfentrazone was first detected in shallow groundwater at 455 days after treatment (DAT), at a concentration of 0.11 ppb. The maximum concentration of sulfentrazone detected in the shallow monitoring wells was 0.86 ppb on 577 DAT. Thereafter, sulfentrazone concentrations in shallow groundwater gradually declined to levels near or below the LOQ of 0.1 ppb by the study's end, 1846 days after treatment.

The first detection of SCA in shallow wells (0.11 ppb) occurred on 302 DAT. The maximum concentration of SCA in shallow wells was 2.50 ppb on 455 DAT. Thereafter, SCA concentrations in shallow groundwater gradually declined to levels near or below the LOQ of 0.1 ppb by the study's end, 1846 days after treatment.

In the 75th percentile study, sulfentrazone exhibited a clear pattern of breakthrough, peak and decline in the soil pore-water. However, only limited detections of sulfentrazone and SCA were observed in the shallow groundwater monitoring wells during the course of the 73-month study.

In the shallow groundwater, sulfentrazone was only detected in five of the eight monitoring wells at levels above the LOD (0.02 ppb) but below the LOQ (0.1 ppb). The maximum detection of sulfentrazone in the shallow wells was 0.09 ppb at 1,149 DAT. These results indicate that in the 75th percentile study, sulfentrazone did not leach appreciably into the shallow groundwater based on the single application of 0.22 lbs a.i./acre (246 g a.i./ha).

SCA was detected in shallow groundwater at concentrations above the LOD (0.02 ppb), but below the LOQ (0.1 ppb) in five of the eight monitoring locations. The maximum SCA concentration in shallow wells was 0.07 ppb at 753 DAT. These results indicate that in the 75th percentile study, SCA did not leach appreciably into the shallow groundwater based on the single application of 0.22 lbs a.i./acre (246 g a.i./ha).

The values reported here should be considered specific to this study and are used to characterise the leaching behaviour. These values are not expected to be representative of potential soil and groundwater concentrations and should not be used for risk assessment purposes.

These results were considered with the previously submitted laboratory column leaching studies, prospective groundwater leaching studies and terrestrial field studies reviewed under ERC2010-08.

4.1 Environmental Risk Characterization

Please refer to ERC2010-08 for a detailed assessment of the potential environmental impacts of sulfentrazone.

4.1.1 Risks to Terrestrial Organisms

A risk assessment has previously been carried out for sulfentrazone agricultural uses. For details, please refer to ERC2010-08. In ERC2010-08, it was identified that an acute oral toxicity study for bees was required. This information was submitted and reviewed. Sulfentrazone was found to be relatively non-toxic to honeybees and is not expected to pose a risk to pollinators.

4.1.2 Risks to Aquatic Organisms

A risk assessment has previously been carried out for sulfentrazone agricultural uses. For details, please refer to ERC2010-08. In ERC2010-08, it was identified that sulfentrazone is persistent and likely to accumulate in aquatic systems and information was required to address whether there is risk from long term exposure to fish. An aquatic field study was reviewed which showed that under field conditions, sulfentrazone is not expected to accumulate in surface aquatic ecosystems and that the chronic aquatic toxicity studies previously submitted adequately addressed the risk. Additional aquatic toxicity information was also submitted for methyl triazole, a photolysis product identified in the aquatic field dissipation studies. The review of this information indicated that methyl triazole is less toxic than sulfentrazone and that it enters the environment at levels less than the parent. The risk assessment and mitigation measures determined for the parent are expected to cover any effects of the methyl triazole.

No additional information is required to address this concern.

5.0 Value

Please refer to ERC2010-08 for a detailed assessment of the value of Authority 480 Herbicide. The information requested from the registrant, as identified in ERC2010-08, was provided to the PMRA for review.

The registrant provided additional efficacy trials conducted in the Prairie Provinces and based on the efficacy information provided, control of kochia, lamb's quarters, redroot pigweed and wild buckwheat was achieved with an application of Authority 480 Herbicide at a rate of 105 to 140 g a.i./ha of sulfentrazone in medium and fine textured soils.

Additional rotational re-cropping trials were also provided and based on the information provided for review the following rotational crops can appear on the Authority 480 label with their respective replant interval: alfalfa (12 months), barley (12 months), canola (24 months), chickpea (anytime), field corn (12 months), sweet and pop corn (24 months), field pea (anytime), flax (anytime), lentils (36 months), sorghum (24 months), soybeans (anytime), sunflowers (anytime), spring and durum wheat (12 months) and winter wheat (16 months).

At the time of registration, a stewardship plan was required to address issues of persistence and leaching of sulfentrazone; the registrant provided a summary of the key points communicated to the growers through a technical bulletin and newsletter from the Pulse Growers association.

The University of Saskatchewan and Agriculture and Agri-Food Canada have developed a soil bioassay for the determination of sulfentrazone residues in soil. In addition, the registrant has developed an Enzyme Linked Immunosorbent Assay (ELISA) method for sulfentrazone that would be made available to growers for analyses of samples from any sulfentrazone contaminated water.

The data submitted to convert Authority 480 Herbicide to full registration are adequate to describe its efficacy for use as a pre-plant or pre-emergence application in chickpea. A single application of Authority 480 Herbicide provides control of wild buckwheat, common lamb's quarters, redroot pigweed, and kochia. The submitted stewardship plan provided adequate information for growers to mitigate the effects of the persistence and leaching of sulfentrazone in soils. Authority 480 Herbicide (Group 14) provides an alternative mode of action to commonly used herbicides for the labelled crops.

Since concerns were identified regarding the persistence of the product in various soils especially under atypical environmental conditions (i.e. drought years), Authority 480 Herbicide is not to be applied in consecutive years (2 years or 24 months between applications) and this period is to be extended in years with below normal precipitation and any re-cropping intervals need also to be extended following periods of drought.

These measures, along with all the warnings present on the label, should help to mitigate the carryover and leaching of sulfentrazone.

6.0 Pest Control Product Policy Considerations

Please refer to ERC2010-08 for pest control product policy considerations.

7.0 Summary

7.1 Human Health and Safety

Based on available published scientific literature, the metabolite SCA is considered to be of equivalent toxicity to the parent compound sulfentrazone. There are no amendments to the previous toxicological review. Please refer to ERC2010-08 for a detailed assessment of the toxicological database for sulfentrazone.

Mixers, loaders, applicators and workers entering treated areas are not expected to be exposed to levels of Authority 480 Herbicide that may result in unacceptable risk when Authority 480 Herbicide is used according to label directions. The personal protective equipment stated on the product label is adequate to protect workers.

The residue definition is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone in primary and rotational crops, except soybean, and is sulfentrazone and 3-hydroxymethyl sulfentrazone in soybean. In animals, the residue definition is sulfentrazone, 3-hydroxymethyl sulfentrazone and 3-desmethyl sulfentrazone. The proposed use of sulfentrazone on chickpeas, and the importation of asparagus, cabbages, commodities in crop subgroup 6C- dried shelled pea and bean (except soybean), horseradish, soybean, sunflowers and mint, do not constitute an unacceptable chronic or acute dietary risk (food and drinking water) to any segment of the population, including infants, children, adults and seniors. Sufficient crop residue data have been reviewed to recommend maximum residue limits, both domestic and import, to protect human health. The proposed MRLs for sulfentrazone in Canada in or on food can be found in PMRL2010-32.

7.2 Environmental Risk

Additional information on the fate of sulfentrazone in the environment has been submitted and was found to adequately address previously identified data gaps for this active ingredient. Environmental concerns have been reduced through environmental statements and mitigation with spray buffer zones on the product label. Predicted levels of sulfentrazone in groundwater were found to be below the level of concern for human exposure via drinking water.

7.3 Value

The data submitted to convert Authority 480 Herbicide to full registration are adequate to describe its efficacy for use as a pre-plant or pre-emergence application in chickpea. A single application of Authority 480 Herbicide provides control of wild buckwheat, common lamb's quarters, redroot pigweed, and kochia. The submitted stewardship plan provided adequate information for growers to mitigate the effects of the persistence and leaching of sulfentrazone in soils. Authority 480 Herbicide (Group 14) provides an alternative mode of action to commonly used herbicides for the labeled crops.

Since concerns were identified regarding the persistence of the product in various soils especially under atypical environmental conditions (i.e. drought years), Authority 480 Herbicide is not to be applied in consecutive years (2 years or 24 months between applications) and this period is to be extended in years with below normal precipitation and any re-cropping intervals need also to be extended following periods of drought.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Sulfentrazone Technical Herbicide and Authority 480 Herbicide containing the technical grade active ingredient sulfentrazone for use on chickpeas in the Prairie Provinces to control a variety of weeds.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

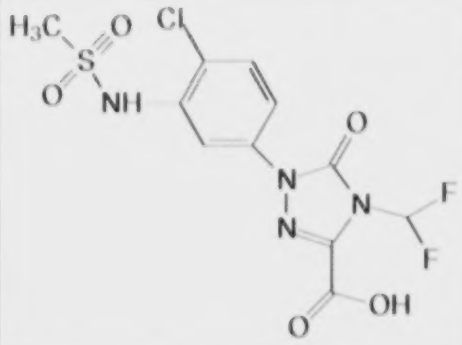
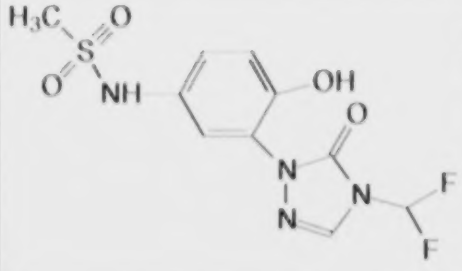
µg	microgram(s)
a.i.	active ingredient
AR	applied radioactivity
cm	centimetre(s)
d	day(s)
DAT	day(s) after treatment
DFOP	double first-order half life
DT_{50}	dissipation time 50% (the dose required to observe a 50% decline in concentration)
DT_{90}	dissipation time 90% (the dose required to observe a 90% decline in concentration)
EC_{50}	effective concentration on 50% of the population
EEC	estimated environmental concentration
FDA	*Food and Drugs Act*
g	gram(s)
ha	hectare(s)
HPLC	high performance liquid chromatography
ID	identification
kg	kilogram(s)
K_{oc}	organic-carbon partition coefficient
K_{ow}	*n* octanol-water partition coefficient
L	litre(s)
lb	pound(s)
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LOD	limit of detection
LOQ	limit of quantitation
mg	milligram(s)
mL	millilitre(s)
MRL	maximum residue limit
MS	mass spectrometry
N/A	not available
NOEC	no observed effect concentration
PGW	prospective groundwater monitoring study
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
ppm	parts per million
RQ	risk quotient
SCA	3-carboxylic acid sulfentrazone
SFO	single first-order half life
$t_{1/2}$	half-life
USEPA	United States Environmental Protection Agency
wt	weight

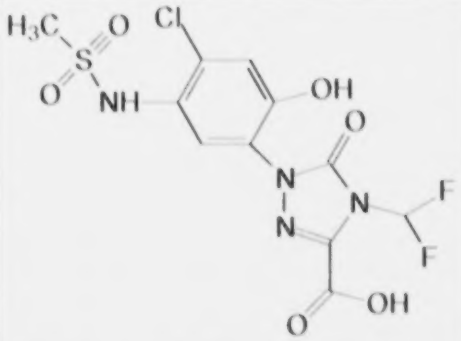
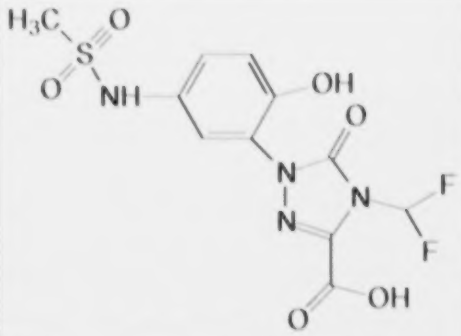
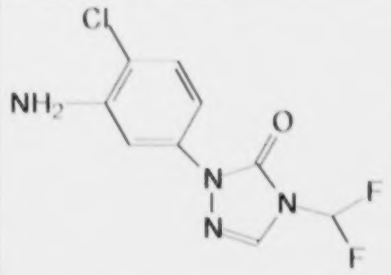
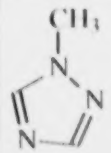
Appendix I Tables and Figures

Table 1 Residue Analysis

Matrix	Method ID	Analyte	Method Type	LOQ	Reference
Soil	N/A	sulfentrazone	HPLC-MS or HPLC-MS-MS	5 ppb	1853397
		3-carboxylic acid sulfentrazone	HPLC-MS or HPLC-MS-MS	5 ppb	
Fish	N/A	sulfentrazone	HPLC-MS-MS	0.05 ppm	1853401
		3-hydroxymethyl sulfentrazone	HPLC-MS-MS	0.05 ppm	

Table 2 Summary of recent submitted information on the phototransformation products formed in water

Common name	Chemical name	Chemical Structure	Maximum Occurrence % AR (day)
M1 mono-dechlorinated-SCA	2'-deschloro-sulfentrazone-3-carboxylic acid		pH 4: - pH 7: 29.5% (12) pH 9: 32.7% (9)
M2 hydroxy-desdichloro-descarboxy-sulfentrazone	2'-hydroxy-2',4'-desdichloro-3-descarboxyl-sulfentrazone		pH 4: 15.6% (9) pH 7: - pH 9: -

Common name	Chemical name	Chemical Structure	Maximum Occurrence % AR (day)
M3 Deschloro-desmethylsulfonyl-desmethyl sulfentrazone	2'-hydroxy-2'-deschloro-sulfentrazone-3-carboxylic acid		pH 4: - pH 7: 7.8% (15) pH 9: -
M4 Hydroxy-desdichloro-sulfentrazone	2'-hydroxy-2',4'-desdichloro-sulfentrazone-3-carboxylic acid		pH 4: 12.8% (12) pH 7: - pH 9: -
M5 Deschloro-desmethylsulfonyl-desmethyl sulfentrazone	2'deschloro-5'-desmethylsulfonyl-3-descarboxyl-sulfentrazone		pH 4: - pH 7: 33.5% (9) pH 9: 41.3% (12)
Methyl triazole	1-methyl-1H-1,2,4-triazole		Aquatic field dissipation study: approx. 15%

- indicates that the transformation product was not measured

Table 3 Fate and Behaviour of Sulfentrazone in the Environment

Property	Test substance	Value	Comments	Reference
Abiotic transformation				
Hydrolysis	SCA	Stable at pH 5, 7 and 9	SCA was stable to hydrolysis at basic, neutral and acidic pHs.	1853403
Phototransformation in water	SCA	pH 4: 10.3 d pH 7: 4.06 d pH 9: 4.21 d	Important route of transformation in the photic zone of aquatic systems. Major transformation products: M1, M2, M3, M4 and M5	1853403
Mobility				
Adsorption / desorption in soil	SCA Sand: Silty clay loam: Sandy loam: Sandy loam:	 K_{oc}: 0 mL/g K_{oc}: 6 mL/g K_{oc}: 0.12 mL/g K_{oc}: 0.11 mL/g	Very high mobility in all soils	1853408
Field studies				
Field dissipation	Sulfentrazone Spartan 4 F	SFO: DT_{50}: 283 d DT_{90}: 941 d DFOP: DT_{50}: 87 d DT_{90}: 1200 d	Persistent. SCA was the only major transformation product measured.	1855870
Aquatic Field Dissipation Study		SFO: DT_{50}: 22 d DT_{90}: 74 d	Slightly persistent. A major transformation, methyl triazole was identified.	1855871
Field leaching-PGW Studies 95th percentile	Sulfentrazone Authority Broadleaf	n/a	Sulfentrazone leaches and slowly transforms to SCA with depth, and that both sulfentrazone and SCA may persist for an extended time (several years) in shallow groundwater.	1485405
Field leaching-PGW Studies 75th percentile	Sulfentrazone Authority Broadleaf	n/a	Sulfentrazone moved downward through the soil and slowly transformed to SCA, with only very low concentrations reaching the groundwater over the 73-month monitoring period.	1649947 1617767

Table 4 Toxicity to Non-Target Species

Organism	Exposure	Test substance	Endpoint value	Degree of toxicity[a]	Reference
Terrestrial Invertebrates					
Earthworms	14 days	Methyl triazole	NOEC and LD_{50} >100 mg a.i./kg dry wt	n/a	1853414
Bee	48 hours Oral	SCA	LD_{50} >100 µg a.i./bee	relatively non-toxic	1853415
Freshwater Species					
Daphnia magna	48 hours Acute	Methyl triazole	EC_{50} >100 mg a.i./L	Practically non-toxic	1853418
Rainbow trout	96 hours Acute	Methyl triazole	LC_{50} >100 mg a.i./L	Practically non-toxic	1853419
Freshwater alga		Methyl triazole	LC_{50} >100 mg a.i./L	Practically non-toxic	1853420
Vascular plants	7 days	Methyl triazole	NOEC >200 mg a.i./L	Practically non-toxic	1853421

Table 5 Screening Level Risk Assessment on Non-Target Species

Organism	Exposure	Endpoint value	EEC	RQ	LOC Exceeded?
Bee	Oral	LD_{50} >100 µg a.i./bee equivalent to 112 kg a.i./bee	140 g a.i./ha	<0.01	No

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

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1853401	2008, Validation of the Analytical Method for the Determination of Sulfentrazone and its Major Metabolite in Fish, DACO: 8.2.2.4

2.0 Human and Animal Health

PMRA Document Number	Reference
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3.0 Environment

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